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10/648,459	08/26/2003	Thomas Yung-Hui Chien	1001.2205101	5094

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,459	Applicant(s) CHIEN ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-21 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-21 and 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification amendment submitted 03/22/10 has been accepted.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4-7, 9, 10, 14-16, 18, 19, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski (6,579,305) in view of Lau (US 5,421,955) and further in view of Stack (US 6,264,683).
4. Regarding claims 1 and 23, Lashinski discloses a stent delivery system (see entire document and for example Fig. 2) comprising: an inner tube (tube defining guide wire lumen) comprising a proximal end and a distal end, the inner tube being disposed within an outer tube (22) with an annular space (25) disposed therebetween, the distal end of the inner tube further comprising a distal tip (see Fig. 2, portion of inner shaft that extends beyond balloon), a heating element (saline fluid indicated by arrows C4:L45-54) positioned around the inner tube proximal to the distal tip, the outer tube comprising a proximal end and a distal end, the distal end of the outer tube being disposed proximally

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to the distal tip of the inner tube and defining a distal end diameter, the distal end of the outer tube being connected to a balloon (27) which extends between the distal end of the outer tube and the distal tip of the inner tube, the balloon being connected to the distal tip of the inner tube (see Fig. 2), the balloon overlying the heating element (saline fluid indicated by arrows), and an expandable stent (28) positioned around the balloon and disposed between the distal end of the outer tube and the proximal edge of the distal tip, wherein the stent is formed of a stent material having a shape memory transition temperature lower than an elevated temperature produced by the heating element so that the stent expands in response to the heating provided by the heating element (C1:L43-62; C4:L43-54). Regarding claim 4: the balloon is also connected to the distal tip of the inner tube (see Figure 2). Regarding claims 5 and 24: the stent is crimped onto the balloon (C4:L2). Regarding claims 6 and 25: the stent comprises nitinol (C1:L45). Regarding claim 7 and 26: the stent is a self-expanding stent (C4:L51 where the stent is shape memory nitinol and expanded by influence of heat). Regarding claim 9: the distal tip of the inner tube is tapered (see Fig. 2). Regarding claim 10, Fischell teaches a distal radiopaque marker (13d) disposed immediately proximal to the distal tip and a proximal radiopaque marker (13p) which is located disposed immediately distal to the distal end of the outer tube (for example as seen in configuration of Fig. 3).

5. Lashinski does not explicitly disclose that the annular space is not in fluid communication with the lumen of the inner tube and an exterior of the balloon. However, Lau discloses a similar process of delivering providing heat to a stent and balloon

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combination to assist in expanding the stent. Lau does this by warming the inflation fluid that is delivered to expand a balloon using a conventional balloon catheter (C6:L45-51 and C4:L26-27) (i.e. an annular lumen that is not in communication with the inner shaft lumen or the exterior of the balloon). While Lashinski provides for leakage of fluid into the vessel in order to maintain the temperature of the fluid in the balloon, Lau discloses a simpler device that performs the same function without the need for fluid leakage. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to simplify the device of Lashinski as taught by Lau in order to simply manufacturing while maintaining its functional intention.

6. Lashinski does not explicitly disclose that the edge diameter of the distal tip of the inner tube and the distal end diameter of the outer tube are equal to or greater than a maximum outer diameter of the stent in an unexpanded form. However, Stack discloses a stent delivery device with an inner tube having a distal tip (20) with a proximal edge diameter and an outer tube defining a distal end diameter, wherein both diameters are equal to or greater than a maximum outer diameter of the stent in an unexpanded form (Figs. 1-4) in order to prevent slippage of the stent and prevent the stent from contacting the vessel wall during delivery (C1:L42-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate retainers on the deliver device of Lashinski to achieve the same advantages.

7. Regarding claim 14: Lashinski discloses the method of deploying an expandable stent in a vasculature system comprising providing the stent delivery device as stated above. Lashinski further discloses the method steps of inserting the stent delivery

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system with the stent in the unexpanded form, into the vasculature system and to a desired position, and heating the stent to expand the stent and causing it to adhere to the vasculature system at the desired position (C4:L43-54); deflating the balloon, and withdrawing the inner and outer tubes and balloon from the vasculature system (it is inherent that the balloon would be deflated and the catheter withdrawn from the vasculature after the stent is delivered to its desired site). Regarding claim 15: during the heating of the stent, the balloon is heated and partially inflated (C4:L43-54).

Regarding claim 16, during the inserting step, the balloon and stent are cooled (relative to the warm temperature applied to the stent during deployment at the site of the stenosis [C4:L45-46]). Regarding claim 18: the heating is performed using warm saline solution delivered through the annular space and into the balloon (see arrows fig. 2, C4:L45-50). Regarding claim 19: the heating is performed using a heating element (the warm saline is considered the heating element).

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski (US 6,579,305) in view of Lau (US 5,421,955) and Stack (US 6,264,683) as applied to claim 1 above, and further in view of Klein (US 6,605,107).

9. Lashinski modified by Fischell does not explicitly disclose that the balloon comprises an elastomeric material. However, Klein discloses that it is old and well known to choose elastomeric material for a balloon in a stent delivery device. It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute elastomeric material so that the balloon can maintain a reduced profile after

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being deflated. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski (US 6,579,305) in view of Lau (US 5,421,955) and Stack (US 2,264,683) as applied to claim 16 above, and further in view of Rabkin (US 6,676,692)

11. Lashinski modified by Fischell does not explicitly disclose the use of a cool saline solution to cool the stent and balloon during delivery. However Rabkin discloses that it is well known in the art to use a cool fluid during delivery to ensure that the stent does not expand prematurely (C18:L13-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this same feature to achieve the same advantage.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski (US 6,579,305) in view of Lau (US 5,421,955) and Stack (US 6,264,683) as applied to claim 19 above, and further in view of Healy (US 6607553).

13. Lashinski modified by Fischell does not further disclose a thermocouple located on the distal end of the inner tube for monitoring the temperature. However Healy discloses the use of a thermocouple for monitoring that the temperature of the stent is high enough to transition the stent without being too high too damage the tissue (C8:L52-67). It would have been obvious to one having ordinary skill in the art at the

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time of the invention to incorporate a thermocouple for the same advantage. Regarding the location of the thermocouple it would have been obvious to one having ordinary skill in the art at the time the invention was made relocate the thermocouple to location that provides the most efficient feedback for its use since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

14. Claims 3, 12, 13, 20, 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski (US 6,579,305) in view of Lau (US 5,421,955) and Stack (US 6,264,683) as applied to claims 1 and 14 above, and further in view of Kasprzyk (US 5,035,694).

15. Lashinski modified by Fischell does not disclose that the heating element is a coil connected to a power line and a return line through which current is supplied to the coil. However Kasprzyk discloses the use of a coil heating element (50, 51) for supplying heat to the immediate area surrounding a balloon (C6:L16-22). The heating element is connected to a power supply (33) via a power line and a return line which are insulated (C4:L52-C5:L25). Kasprzyk does not disclose the use of supplying heat to the surface of a balloon for expanding a stent but rather discloses supplying heat to the surface of a balloon for treating a stenosis. However, it would be well within the skill of the ordinary artisan to look to Kasprzyk for an alternative manner of providing heat to the surface of a balloon. Doing so would allow the operator more control over the change in temperature and thus more control over the expansion rate of the stent thereby ensuring accurate placement of the stent during delivery. The substitution of one known

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element (heating coil) for another (warm saline solution) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution would have yielded predictable results, namely, a manner of heating the stent for expansion.

16. With respect to claim 27, Lashinski modified by Fischell discloses the step of heating the stent to expand the stent and causing it to adhere to the vasculature system at the desired position. The combination of Kasprzyk further provides the missing limitation of providing heat by supplying current to the heating element.

17. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski (US 6,579,305) in view of Lau (US 5,421,955) and Stack (US 6,264,683) and Kasprzyk (US 5,035,694) as applied to claim 27 above, and further in view of Rabkin (US 6,676,692)

18. Lashinski modified by Fischell and Kasprzyk does not disclose the use of a cool saline solution to cool the stent and balloon during delivery. However Rabkin discloses that it is well known in the art to use a cool fluid during delivery to ensure that the stent does not expand prematurely (CC18:L13-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this same feature to achieve the same advantage.

19. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski (US 6,579,305) Lau (US 5,421,955) and Stack (US 6,264,683) and Kasprzyk

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(US 5,035,694) as applied to claim 27 above, and further in view of Healy (US 6607553).

20. Lashinski modified by Fischell and Kasprzyk does not further disclose a thermocouple located on the distal end of the inner tube for monitoring the temperature. However Healy discloses the use of a thermocouple for monitoring the temperature is high enough to transition the stent without being too high too damage the tissue (C8:L52-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a thermocouple for the same advantage. Regarding the location of the thermocouple it would have been obvious to one having ordinary skill in the art at the time the invention was made relocate the thermocouple to location that provides the most efficient feedback for its use since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 3-10, 12-21, and 23-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/16/10